

**REMARKS**

Upon entry of the foregoing amendment, claims 20, 22, 23, 25-29, 31, 33, 34, 36 and 40-43 are pending in the application.

Claims 1-19, 21, 24, 32, 35, 37-39 and 44 were previously cancelled. Claim 30 is newly cancelled herein. Claims 1-19, 21, 24, 30, 32, 35, 37-39 and 44 are cancelled without prejudice or disclaimer of the cancelled subject matter. Applicants reserve the right to pursue the cancelled subject matter in one or more continuing or divisional applications.

Claims 20, 22 and 31 have been amended. Support for the amendments to claims 20 and 22 ("wherein the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation") is found, for example, in previous claim 30, and elsewhere throughout the specification.

Claim 31 is amended herein to claim correct claim dependency from claim 22 in view of the cancellation of claim 30.

This amendment is not believed to introduce new matter and entry is respectfully requested.

**WITHDRAWN REJECTIONS**

Applicants acknowledge with thanks the withdrawal of the rejection of claims 20, 22, 28, 30, 31 and 40-43 under 35 U.S.C. § 102(b) as anticipated by Tsunenaga et al. (U.S. Patent No. 5,137,875).

Applicants also acknowledge with thanks the withdrawal of the rejection of claims 20, 22, 23, 25-28 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Suzuki et al. (U.S. Patent No. 6,197,326).

#### **OBJECTIONS**

Claims 30, 31, 33 and 36 are objected to as being dependent upon a rejected base claim. Applicants acknowledge with thanks the decision by the Examiner that claims 30, 31, 33 and 36 are free of the prior art. In view of the foregoing, claims 20 and 22 are newly amended to include the text of claim 30. As such, claims 20, 22 and claims dependent therefrom, are believed to be in condition for allowance.

#### **REJECTIONS UNDER 35 U.S.C. § 103(a)**

Claims 20, 22, 23, 25-29, 34 and 40-43 were rejected under 35 U.S.C. § 103(a) as unpatentable over Suzuki et al. (U.S. Patent No. 6,197,326, filed October 14, 1998) ["Suzuki"] in view of Igari et al. (U.S. Patent No. 5,416,071, issued on May 16, 1995) ["Igari"]. This rejection is respectfully traversed. Claims 20 and 22 are newly amended herein.

The Office arguments at pages 3-4 are briefly summarized as follows. Suzuki is cited for allegedly teaching a formulation for the treatment of arthropathy comprising microcapsules of a biocompatible high molecular weight substance such PLGA, a homopolymer or copolymer of lactic acid, glycolic acid, caprolactone and others, a drug, administering the microcapsules by injection by suspending the microcapsules in a dispersion medium, use of injection grade water as the dispersion medium, a buffer, an isotonicity, and, a microcapsule dispersing medium containing hyaluronic acid. The Office states, however, that Suzuki fails to teach the concentration of hyaluronic acid in the formulation. Allegedly, Igari cures the deficiencies of Suzuki. Igari allegedly teaches a pharmaceutical composition suitable for injection comprising erythropoietin or other

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biological agents such as NGF and hyaluronic acid, a high molecular weight compound know to be biodegradable and injectable at a concentration of 0.01% to 3%.

According to the Office, it would have been obvious to one of ordinary skill in the art to combine the two references to administer a biologically active agent by injecting a formulation comprising hyaluronic acid, buffer and a microcapsule of a biocompatible polymeric substance and a biologically active agent as taught by Suzuki using the concentration of hyaluronic acid as taught by Igari because the hyaluronic acid at the concentration of 0.01% to 3% would allow the formulation to be easily administered using a small gauge needle such as 26G.

Applicants disagree with the conclusion of the Office. However, claims 20 and 22 are newly amended herein in order to proceed to allowance and issue. Claims 20 and 22 as newly amended herein now recite the phrase “wherein the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation.” Neither Suzuki, or Igari, taken alone or together, teach or suggest a polymeric concentration of 1 mg/mL to about 500 mg/mL as now recited in claims 20 and 22. The Office explicitly acknowledges this fact in its objection to, but not rejection of, claims 30, 31, 33 and 36.

Thus, because Suzuki and Igari fail to render obvious independent claims 20 and 22 as amended, the documents fail to render obvious claims 23, 25-29, 34 and 40-43, dependent therefrom.

In view of the arguments above, the amendments to the claims and the Examiner’s indications that claims 30, 31, 33 and 36 are allowable but for depending from rejected claims, reconsideration and withdrawal of the rejection is respectfully requested.

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**CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.

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